March 30, 2006

Ken Nitschke, DABT
EH&S Toxicology & Environmental Research
The Dow Chemical Company
1691 North Swede
Midland, MI 48674

Dear Dr. Nitschke:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Tetrahydrobenzaldehyde posted on the ChemRTK HPV Challenge Program Web site on January 19, 2005 I commend The Dow Chemical Company for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Dow advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Mark Townsend, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
Tetrahydrobenzaldehyde

Summary of EPA Comments

The sponsor, The Dow Chemical Company, submitted a test plan and robust summaries to EPA for Tetrahydrobenzaldehyde (CAS No.100-50-5) dated December 17, 2004. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 19, 2005.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. The submitter needs to indicate whether the vapor pressure value of 2.3 hPa is estimated or measured, and address deficiencies in the robust summaries.

2. Environmental Fate. EPA reserves judgement on the adequacy of data submitted for the biodegradation endpoint until more information is provided.

3. Health Effects. Inadequate data were submitted for reproduction toxicity, and no data were submitted for the developmental toxicity endpoint. However, EPA agrees that, owing to the corrosive nature of the sponsored substance, no further testing is needed for the reproductive/developmental toxicity endpoints.

4. Ecological Effects. The duration of the fish study was not standard. Critical information is missing from the fish and invertebrate robust summaries. The submitter also needs to provide measured data on toxicity to algae or submit adequate existing analog data.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the Tetrahydrobenzaldehyde Challenge Submission

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The data provided by the submitter for melting point, boiling point, partition coefficient, and water solubility are adequate for the purposes of the HPV Challenge Program.

Vapor pressure. The submitter provided two values. The test plan indicates that the value of 2.97 hPa was "calculated using an accepted estimation method, which accurately estimates the vapor pressure measured at a higher temperature (164 °C)." While the value is adequate, the submitter needs to add a clearer version of this information to the robust summary as well as the measured vapor pressure at this higher temperature. For the value of 2.3 hPa from a company MSDS, the submitter needs to indicate in the robust summary whether this value is estimated or measured.

Environmental Fate (photodegradation, stability in water, biodegradation and fugacity)

The data provided by the submitter for photodegradation and fugacity are adequate for the purposes of the HPV Challenge Program.

Stability in water. EPA agrees that this substance is not susceptible to hydrolysis. However, oxidation to the carboxylic acid will occur at some rate. The submitter needs to include a technical discussion in the robust summary with an indication of the expected oxidation rate.

Biodegradation. The data provided by the submitter are not sufficient for EPA to make an accurate judgement as to the adequacy of this endpoint. The submitter needs to provide the following information: initial concentration of test material, source and concentration of the inoculum, temperature of incubation, and analytical method used to measure biodegradation. This information is needed in order to describe an adequate biodegradation test. If the submitter cannot supply this information, the robust summary will be considered inadequate for purposes of the HPV Challenge Program and the submitter will need to provide measured ready biodegradation data for this chemical following OECD TG 301.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, reproductive/developmental toxicity)

General. The test plan mentions that the sponsored substance is a closed system intermediate (CSI) but does not include a formal claim of CSI status.

Adequate data were submitted for the acute, repeated-dose and genetic toxicity endpoints for the purposes of the HPV Challenge Program. No data were submitted for the developmental toxicity endpoint.

Reproductive/Developmental toxicity. The data for the reproductive toxicity endpoint are from a 14-day repeated-dose inhalation study, which is an inadequate duration for this endpoint. The submitter proposes no testing for the reproductive/developmental toxicity endpoints because of the corrosivity of the test substance and because there were no significant treatment-related effects to reproduction noted in the repeated-dose inhalation toxicity study cited above. EPA agrees that, owing to the corrosive nature of the sponsored substance, no further testing is indicated for these endpoints.

Ecological Effects (fish, invertebrates, and algae)

Fish. The submitted data are inadequate in part because concentration losses were not factored into the LC50 value. This is likely to underestimate toxicity. A reasonable estimate of oxidation loss should be applied if possible. In addition, the test duration is excessive. Elements of the standard 96-hour acute toxicity test need to be provided including mean measured concentrations and key water chemistry elements, such as water hardness and dissolved oxygen content over the test duration. If data corresponding to a 96-hour acute test cannot be extracted from the 14-day test, the submitter needs to conduct testing according to OECD TG 203 or provide an ECOSAR value supported by adequate existing measured data on a suitable analog.

Invertebrates. The data are inadequate pending receipt of a revised robust summary that includes the following study details: pH of controls and measured treatment concentrations at time zero and at 96 hours, dissolved oxygen content, water temperature, and water hardness. If this information is not available, the submitter needs to conduct testing on this chemical according to OECD TG 202 or provide an ECOSAR value supported by adequate existing measured data on a suitable analog.

Algae. The submitted ECOSAR-estimated value needs to be supported by adequate experimental analog data in robust summary format to be considered adequate for the purposes of the HPV Challenge Program.

Specific Comments on the Robust Summaries

None.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.